UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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DURAMED PHARMACEUTICALS, INC., Plaintiff, v. WATSON LABORATORIES, INC., Defendant.	3:08-cv-0116-LRH-RAM ORDER

Before the court is plaintiff Duramed Pharmaceuticals, Inc.'s ("Duramed") motion for summary judgment filed on August 14, 2009. Doc. #175.[1] Defendant Watson Laboratories, Inc. ("Watson") filed a response on September 10, 2009. Doc. #187. Thereafter, Duramed filed a reply on September 30, 2009. Doc. #199.

Also before the court is Duramed's motion to exclude. Doc. #177.

I. Facts and Background

Plaintiff Duramed is a pharmaceutical company that researches, patents, commercializes, markets, and distributes brand name pharmaceutical drugs. On December 5, 2001, Duramed filed a patent application for a new extended contraceptive regimen[2] to be marketed under the brand name

[1] Refers to the court's docket number.

[2] Combined oral contraceptive products have been on the market since the early 1960s. These early contraceptive regimens administered the pill on a 28-day standard cycle. For the first 21 days, a patient would

Seasonique. In contrast to other regimens, Seasonique follows the active combined contraceptive cycle with seven (7) days of low-dose estrogen in place of the hormone-free placebo pill. On January 22, 2008, Duramed was issued U.S. Patent No. 7,320,969 ("the '969 patent") for the Seasonique regimen.

Defendant Watson is a pharmaceutical company that develops generic versions of name brand drugs for the market. Watson filed a new drug application with the FDA requesting approval to make and market a generic equivalent to Duramed's Seasonique product.

Subsequently, on March 6, 2008, Duramed filed the instant action against Watson for infringement of the '969 patent. Watson asserted three affirmative defenses: (1) non-infringement; (2) inequitable conduct; and (3) obviousness. On December 12, 2008, the court dismissed Watson's inequitable conduct defense for failure to pursue. Doc. #68. Further, Watson stipulated to dismiss its non-infringement defense stating that it infringed the '969 patent to the extent that the patent is found valid. Doc. #91.

Thereafter, Duramed filed the present motion for summary judgment on Watson's remaining affirmative defense, obviousness. Doc. #175. Along with the motion for summary judgment, Duramed also filed the present motion to exclude Watson's expert testimony. Doc. #177.

II. Legal Standard

Summary judgment is appropriate only when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In assessing a motion for summary judgment, the evidence, together

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take a combined active pill which included estrogen and other hormones designed to prevent pregnancy. This period was followed by a 7-day hormone-free interval in which a patient took a placebo pill in which no hormones were administered. This 28-day pill cycle would be repeated as desired to help prevent pregnancy.

An extended contraceptive regimen is the same as a traditional contraceptive regimen (a period of combined hormone pills followed by a hormone-free period) except that the cycle is elongated so that the active combined pills are taken continuously for up to three months. The standard 7-day hormone free interval follows.

with all inferences that can reasonably be drawn therefrom, must be read in the light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *County of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1154 (9th Cir. 2001).

The moving party bears the burden of informing the court of the basis for its motion, along with evidence showing the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). On those issues for which it bears the burden of proof, the moving party must make a showing that is "sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party." *Calderone v. United States*, 799 F.2d 254, 259 (6th Cir. 1986); *see also Idema v. Dreamworks, Inc.*, 162 F. Supp. 2d 1129, 1141 (C.D. Cal. 2001).

To successfully rebut a motion for summary judgment, the non-moving party must point to facts supported by the record that demonstrate a genuine issue of material fact. *Reese v. Jefferson Sch. Dist. No. 14J*, 208 F.3d 736 (9th Cir. 2000). A "material fact" is a fact "that might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Where reasonable minds could differ on the material facts at issue, summary judgment is not appropriate. *See v. Durang*, 711 F.2d 141, 143 (9th Cir. 1983). A dispute regarding a material fact is considered genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Liberty Lobby*, 477 U.S. at 248. The mere existence of a scintilla of evidence in support of the non-moving party's position will be insufficient to establish a genuine dispute; there must be evidence on which the jury could reasonably find for the non-moving party. *See id.* at 252.

III. Discussion

A. Motion to Exclude

As part of Watson's defense, Watson retained Dr. Michael A. Thomas ("Thomas") as its expert witness and Dr. Norman Barwin ("Barwin") as a fact witness. Duramed took both Dr. Thomas and Dr. Barwin's depositions. During the depositions, both doctors testified that they had

personally prescribed the same extended contraceptive regimen as that listed in Duramed's patent application (including a 7-day pill cycle containing unopposed estrogen instead of the traditional hormone-free cycle) prior to Duramed filing the application. Duramed has moved to exclude certain aspects of the doctors' testimony arguing that the testimony is uncorroborated.

As a general rule, corroboration of oral testimony regarding prior invention or use is required before the evidence is admissible. *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1217 (Fed. Cir. 2002); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371 (Fed. Cir. 1998). To corroborate oral testimony, a witness must provide reliable documentary or physical evidence that is made contemporaneously with the innovative process. *Texas Digital Sys., Inc.*, 308 F.3d at 1218. The corroboration requirement applies to the obviousness defense. *See TypeRite Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1159 (Fed. Cir. 2004).

In opposition, Watson argues that Drs. Thomas and Barwin are not (and do not claim to be) inventors of the patent-in-suit and that they have no stake in the litigation. Thus, Watson argues that Drs. Thomas and Barwin are not interested witnesses and therefore corroboration of their testimony is not required. However, just like an interested witness, "uninterested witnesses are also subject to the corroboration requirement." *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1368 (Fed. Cir. 1999). This is because "a witness who testifies to antedating the invention of the patent-in-suit can be expected to derive a sense of professional or personnel accomplishment in being the first in a field, and in this sense is not uninterested in the outcome of the litigation, even if that witness is not claiming entitlement to a patent." *Id*. Accordingly, the corroboration requirement is applicable to Drs. Thomas and Barwin.

In his expert report and deposition, Dr. Thomas testified that prior to December 2001, he prescribed estrogen as part of a hormone replacement therapy during the seven days of a traditional hormone-free interval. He further testified that his purpose in prescribing estrogen was to reduce patient headaches caused by estrogen withdrawal.

Dr. Thomas has not corroborated his testimony with any documentation that he actually prescribed estrogen during the traditional hormone-free period. When questioned during his deposition, Dr. Thomas stated that he didn't have any patient records or any prescription logs that would support his claim. Further, he was unable to identify any of his myriad publications that might mention the clinical practice he claimed he performed. Therefore, his testimony is uncorroborated and shall be excluded from examination of the motion for summary judgment.

Dr. Barwin testified similarly to Dr. Thomas in that he prescribed unopposed estrogen during the traditional hormone-free interval prior to 2001. Like Dr. Thomas, Dr. Barwin has no evidentiary corroboration. Moreover, despite teaching medical courses regarding oral contraceptives during the time he allegedly prescribed unopposed estrogen, Dr. Barwin admitted he never once taught his students to prescribe estrogen during the placebo period. Accordingly, Dr. Barwin's testimony is uncorroborated and the court shall likewise exclude the testimony from consideration of the summary judgment motion.

B. Obviousness

An issued patent is presumed valid by statute. *See* 35 U.S.C. § 282. A defendant proffering the affirmative defense of obviousness bears the burden to prove the patent is obvious under 35 U.S.C. § 103 by clear and convincing evidence. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001); *see also Finnigan Corp.*, 180 F.3d at 1365. An invention is obvious when it "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement. *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976). Comparatively, an invention is not obvious "where vague prior art does not guide an inventor toward a particular solution." *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009).

To prove obviousness, a defendant must show that a person of ordinary skill in the art would have had a reason in the relevant field to combine the particular elements or technologies in

the way the claimed new invention does. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). A person of ordinary skill in the art is a person presumed to think "along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). Thus, to establish that the '969 patent was obvious, Watson must show by clear and convincing evidence that before Duramed's application, a person of ordinary skill in the art would have had a reason to take what was known in the art at the time and modify it to arrive at the '969 patent specifications. *See, e.g, Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

Here, Watson argues that a person of ordinary skill would have had a reason to add a small amount of unopposed estrogen during the traditionally hormone-free period to alleviate estrogen withdrawal headaches identified in prior art references analyzed by expert Dr. Thomas. Dr. Thomas opines that it was well known and documented prior to December 2001, that long-term exposure to estrogen created estrogen withdrawal headaches during the hormone-free period and that small doses of estrogen could help alleviate those headaches. Thus, Dr. Thomas opines that a person of ordinary skill would have had a reason to modify the traditional hormone-free interval with unopposed estrogen and thereby reach the same regimen as the '969 patent.

Watson's Prior Art References[3]

1. Kovacs Article

Watson's prominent piece of prior art is an article, entitled "A Trimonthly Regimen for Oral Contraceptives," published in 1993 by Dr. Gabor T. Kovacs ("Kovacs"), a professor at the Monash University Department of Obstetrics and Gynecology. In his article, Dr. Kovacs describes what has

[3] Watson identifies several prior art references in order to show the patent is obvious. The court has identified the three most significant pieces of prior art in the order based on the parties' time spent arguing and analyzing the prior art references in the motion briefing, expert reports, and at oral argument. The court finds the remaining prior art references are cumulative of those addressed in this order and do not provide any new evidence to the court on the issue of obviousness.

become known as the Kovacs' regimen: the administration of 84 days of active combined pills to prevent pregnancy followed by a 7-day hormone-free interval.

Dr. Thomas relied on the Kovacs regimen in his expert report to conclude that the '969 patent was obvious because the Kovacs article identifies that women undertaking extended contraceptive regimens experience headaches. Thus, a person of ordinary skill would be motivated to modify the Kovacs regimen to add unopposed estrogen in light of the article's acknowledgment that the regimen may result in headaches in some women.

However, the Kovacs article describes the associated headaches as "scattered throughout the cycle" rather than arising from the hormone-free interval. By the article's own admission, the headaches are not necessarily a symptom of estrogen withdrawal. Further, the article makes no mention of unopposed estrogen whatsoever. Accordingly, the article does not provide clear and convincing support for Watson's claim that a practitioner faced with a patient suffering from headaches associated with the regimen would naturally come to the conclusion of adding unopposed estrogen to help maintain hormone levels.

2. Sulak Article

Duramed's expert, Dr. Patricia Sulak ("Sulak"), co-authored a paper on the effects and symptoms of hormone withdrawal. Dr. Thomas identifies the article as prior art referencing the effects of contraceptive regimens in causing migraine headaches. The article, entitled "Extending the Duration of Active Contraceptive Pills to Manage Hormone Withdrawal Symptoms," was published in 1997.

Watson argues that the Sulak article establishes that patients suffer migraine headaches from hormone withdrawal: "[u]nfortunately, some patients taking [oral contraceptives] continue to have problems during the pill-free interval, including dysmenorrhea, menorrhagia, and migraine headaches." Doc. #175, Exhibit 5. Further, Watson argues that the article postulates about the possibility of unopposed estrogen as a possible solution to hormone withdrawal symptoms. Thus,

Watson argues that a person of ordinary skill would have a reason to provide unopposed estrogen during the hormone-free period in order to reduce the symptoms associated with hormone withdrawal, including headaches.

Although the Sulak article is the first prior art to identify headaches as a symptom of hormone withdrawal during the traditional hormone-free period, the Sulak article, contrary to Watson's position, does not specifically address the addition of unopposed estrogen. The article was specifically limited to testing prolonging the use of active combined pills:

> *Objective*: To test the hypothesis that extending the number of consecutive active oral contraceptives (OC)s given will decrease the frequency of menstrual-related problems including dysmenorrhea, menorrhagia, premenstrual-type symptoms, and menstrual migraines.

Doc. #175, Exhibit 5. Further, Sulak "hypothesized that women with hormone withdrawal symptoms during the pill-free interval would find acceptable the postponement of menses by extension of the duration of active pills and would experience a decrease in the frequency of their symptoms." *Id*. Thus, the Sulak article tests, and suggests, extending the duration of a pill cycle to alleviate withdrawal symptoms arising during the hormone-free period.

Sulak's reference to the possibility of using unopposed estrogen is as a "theoretical" solution; one of a myriad of untested possible solutions that requires further testing. A person of ordinary skill, who is not an innovator in the field, would not be persuaded to add unopposed estrogen when the published study identifies it as a theoretical possibility that has not yet been tested and offers a different, tested solution in extending the overall regimen. Accordingly, the court finds that the Sulak article does not show by clear and convincing evidence that a person of ordinary skill would have added unopposed estrogen to the traditional hormone-free interval to alleviate the hormone withdrawal symptoms that arise during that period.

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3. '749 Patent

Patent 6,027,749 ("the '749 patent") was issued on February 22, 2000. The patent describes a two-stage contraceptive regimen. Stage one is a variable dosage pill that is administered for at least 25 days and up to 77 days. Stage two is another variable dosage pill of unopposed estrogen that is administered for 5, 6, or 7 days. The two stages provide for a variable length of time for a cycle anywhere from 30 days to 84 days. The patent also identifies several products that are produced at different hormone levels.

Watson argues that the '749 patent contains the exact dosage levels identified in Duramed's '969 patent for the unopposed estrogen pill. Thus, Watson argues that in light of the Sulak article identifying unopposed estrogen as a possible solution for hormone withdrawal symptoms, a person of ordinary skill would choose to combine these references to alleviate hormone withdrawal symptoms and would thereby reach the same regimen as the '969 patent.

However, the '749 patent discloses a variety of dosage levels and cycle lengths and, as such, does not teach any one specific combination that would establish consistent knowledge in the community. The article provides nearly all possible combinations of differing dosage levels based on a woman's previous contraceptive regimen and patient history. Further, the article provides no reference or basis to a practitioner on the effects of adding unopposed estrogen to the end of an extended regimen in regards to hormone withdrawal headaches.

4. Doctors' Testimony

Even if the court did not exclude Drs. Thomas and Barwin's testimony of prior use, their testimony does not satisfy Watson's burden to show that the patent was obvious by clear and convincing evidence. Dr. Barwin is a Canadian practitioner and, as such, his testimony of prior use cannot act as a prior art reference as a matter of law. *See* 35 U.S.C. § 102(b) (defining use of a claimed invention as prior art only if that use is in the United States).

As to Dr. Thomas' testimony of his prior use of unopposed estrogen, the court finds that

Dr. Thomas is not a person of ordinary skill in the art. Dr. Thomas is a tenured professor who specializes in the study of reproductive endocrinology and infertility in the Department of Obstetrics and Gynecology at the University of Cincinnati College of Medicine in Cincinnati, Ohio. Dr. Thomas has an extensive publication history in the area of endocrinology encompassing more than one hundred articles.

Additionally, Dr. Thomas is an active participant in research and study grants in the field of endocrinology. He is listed as a principal or co-investigator on over a dozen research grants. Thus, Dr. Thomas is far from the ordinary practitioner who is presumed to think "along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights." *Am. Cyanamid Co.,* 774 F.2d at 454. Accordingly, Dr. Thomas' testimony of prior use cannot establish what a person of ordinary skill in the field knew at the time, nor why a person of ordinary skill would modify the traditional hormone-free period to arrive at the '969 patent specifications of adding unopposed estrogen.

C. Conclusion

As examined above, the prior art references that Watson relies upon fail to establish that unopposed estrogen was a natural and logical solution to hormone withdrawal headaches. None of the prior art references Watson identifies provide data showing the actual effects of prescribing unopposed estrogen, at any dose, on estrogen withdrawal headaches. After examining all the prior art Watson identifies, the court finds that Watson has not shown by clear and convincing evidence that a person of ordinary skill would have had a reason to add unopposed estrogen to the traditional hormone-free period. *See KSR Int'l Co.*, 550 U.S. at 418. Accordingly, the court finds that the '969 patent was not obvious as a matter of law.

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IT IS THEREFORE ORDERED that plaintiff's motion for summary judgment (Doc. #175) is GRANTED.

IT IS FURTHER ORDERED that plaintiff's motion to exclude (Doc. #177) is GRANTED.

IT IS FURTHER ORDERED that the clerk of court shall enter judgment accordingly.

IT IS SO ORDERED.

DATED this 31st day of March, 2010.

LARRY R. HICKS
UNITED STATES DISTRICT JUDGE